

## REMARKS

Claims 1-20 have been canceled without prejudice or disclaimer. Claims 21-22 have been previously withdrawn and claims 23-42 have been added and therefore are pending in the present application.

Applicants respectfully submit that the present amendment presents no new issues or new matter and places this case in condition for allowance. Accordingly, Applicants request reconsideration of the application in view of the above amendments and the following remarks.

This amendment, among other things, corrects the informalities objected to by the Examiner in the previous Office Action. Claim 1 has been deleted and replaced by claim 23, which corrects the informalities pointed out by the Examiner in the last Office Action and incorporates the limitations of old claim 3 and 7. It is now directed toward a stopper comprising an injection mouldable material made from 70-90% by weight of butyl rubber and 30-10% by weight of a thermoplastic polymer. The new claims 34 and 35, which correspond to old claims 15 and 16, have been reworded to address the Examiner's comments about indefiniteness. Additionally, those claims reciting a shore hardness have been rewritten as new claims that incorporate the appropriate ASTM standard (i.e. ASTM D2240, 5 sec., 1991).

In the previous Office Action, the Examiner withdraw from further consideration claims 21 and 22 and rejected claims 1-20 under 35 USC 102 in view of US 4,444,330 to Kasai et al. ("the '330 patent"). Applicants respectfully aver that the '330 patent relates to a medical container stopper made from an injection mouldable blend of 30 to 90% by weight of a butyl based rubber and 70 to 100 % by weight of a thermoplastic elastomer and at the most 30% by weight of an olefin-based polymer.

Present claim 23, which corresponds, at least in part, to old claim 1, concerns a stopper comprising a butyl based rubber and a thermoplastic polymer comprising an injection mouldable material made from 70-90% by weight of butyl rubber and 30-10% by weight of a thermoplastic polymer. Clearly, the ranges of the two components of the present invention are different from the ranges of the cited documents and thus concerns a completely different composition. Claim 23 is therefore novel over the '330 patent.

Applicants respectfully note that while the Examiner assumes that the stopper of the '330 patent has a hardness of 40-80 shore, there are a number of factors influencing the hardness of a given material blend. These are, for example, the amount and types of additives and/or fillers comprised in the blend, and the strength with which the rubber has been vulcanized. All of these factors play a role in the resulting hardness of the material blend. There are no precise teachings in the '330 patent concerning the amount and types of additives/fillers, nor any information concerning the vulcanization step. Thus, the '330 patent does not either explicitly or inherently teach a stopper having a shore hardness of 40-80. Moreover, it is not obvious to the skilled person that the material of the '330 patent has a shore value of 40-80.

As applicants have noted in their disclosure, one of the objective technical problems to be solved by their present invention is to provide a stopper material for use in medical containers having superior properties of reducing leakage of substances from the stopper into the solution, such as a medical solution, and at the same time have high barrier properties against substances from the solution (see page 1, lines 12-15).

In column 5, lines 53-56, the '330 patent describes that the stopper does not contain additives that might cause elution and thereby pollution of the solution inside the container. Further, the '330 patent describes that the stopper material has improved gas barrier properties, which are due to the presence of the filler component (see column 3, lines 51-54). However, the '330 patent is silent with respect to further barrier properties of the stopper material, such as barrier properties against water and m-cresol and does not mention the problem of substances leaking from the solution over time.

Within the technical field of plastic and rubber materials it is common general knowledge that butyl based rubber has a low permeability for oxygen and water. This has made butyl based rubber a popular material for use in the manufacture of closure means for medical containers, such as stoppers. It is also generally known that a thermoplastic polymer, such as polypropylene is a "stiffer" material compared to butyl based rubber alone. Since one of the objects of the present invention is to provide a material having good mechanical sealing properties, i.e. a material which can be used as a stopper in a container and wherein the stopper and container are in close contact to avoid leakage of substances from the container, the conventional choice of material would be of a

softer material. As described on page 8, lines 22-32 the general belief is that the softer the stopper material the better its capacity to be in close physical contact with a container. However, the present invention has proven otherwise in that the present stopper is of a harder material than for example a stopper made from a butyl based rubber alone. Yet, the present material has preserved the leakage and barrier properties which are usually only characteristic for a butyl based rubber.

A skilled person looking to solve the problem of reducing leakage and improve barrier properties would therefore not look to the '330 patent for a solution to reducing leakage. And even if a skilled artisan were to look there for a solution, the artisan would not find the solution claimed by applicants. The '330 patent does not explicitly or inherently disclose --or even suggest-- the specific combination of stopper materials within the ranges given by the present invention, as defined by the pending claims. In fact, by selecting the stopper materials within the ranges given by the present invention the skilled person would expect a material having poor barrier properties and thus expect the material to be unsuitable for use in medical containers (see page 8, lines 1 1-32).

Accordingly, the present invention is not anticipated by anything explicitly or inherently disclosed by the '330 patent.

### **Conclusion**

In view of the above, Applicants respectfully submit that all claims are in condition for allowance. The Commissioner is hereby authorized to charge any fees in connection with this application and to credit any overpayments to Deposit Account No. 14-1447.

The Examiner should feel free to contact Applicants' attorney if there are any questions concerning this amendment or application.

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Respectfully submitted,



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